



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPP-2018-0265; FRL-10000-29]**

### **Antimicrobial Performance Evaluation Program (APEP): Draft Risk-Based Strategy to Ensure the Effectiveness of Hospital-Level Disinfectants; Notice of Availability and Request for Comments**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA is announcing the availability of and soliciting public comment on the draft document, “Antimicrobial Performance Evaluation Program (APEP): A (Draft) Risk-Based Strategy to Ensure the Effectiveness of Hospital-Level Disinfectants” (hereafter referred to as the draft Strategy). This draft Strategy was developed by the EPA Office of Chemical Safety and Pollution Prevention (OCSPP) in response to the EPA Office of Inspector General (OIG) report titled: “EPA Needs a Risk-Based Strategy to Assured Continued Effectiveness of Hospital-Level Disinfectants.” The draft Strategy provides a framework to ensure that registered hospital-level disinfectants and tuberculocide products continue to meet Agency efficacy standards once they are in the marketplace.

**DATES:** Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2018-0265, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you

consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For general information contact:* Kristen Willis, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, Antimicrobials Division, 2777 S. Crystal Drive, Arlington, VA 22202; telephone number: (703) 347-0515; email address: [willis.kristen@epa.gov](mailto:willis.kristen@epa.gov).

*For technical information contact:* Tajah Blackburn, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, Antimicrobials Division, 2777 S. Crystal Drive, Arlington, VA 22202; telephone number: (703) 347-0260; email address: [blackburn.tajah@epa.gov](mailto:blackburn.tajah@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Introduction**

#### *A. Does this Action Apply to Me?*

This action is directed to the general public. This action may be of interest to health care/hospital professionals and all entities who have EPA registered antimicrobial products that are available in the marketplace, particularly those with products that make hospital disinfectant claims (e.g., claims against *Staphylococcus aureus* and *Pseudomonas aeruginosa*) and other

claims for notable public health pests (e.g., *Clostridium difficile*, methicillin resistant *Staphylococcus aureus*, *Mycobacterium* spp.). The Agency has not attempted to describe all specific entities that may be affected by this action. For questions regarding the applicability of this action, please consult the technical contact listed under “**FOR FURTHER INFORMATION CONTACT**” section of this notice.

*B. What is EPA’s Authority for Taking this Action?*

This action is issued under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136 *et seq.* and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a.

*C. What Action is the Agency Taking?*

EPA is announcing the availability of and opportunity for public comment on the document, titled “Antimicrobial Performance Evaluation Program (APEP): A (Draft) Risk-Based Strategy to Ensure the Effectiveness of Hospital-Level Disinfectants.”

*D. What Should I Consider as I Prepare My Comments for EPA?*

The following should be considered when preparing comments for submission to EPA:

1. *Submission of Confidential Business Information (CBI).* Do not submit CBI to EPA through regulations.gov or email. If submission of CBI is necessary, it should be mailed directly to EPA. Information that is claimed to be CBI should be clearly indicated. For CBI information submitted as a disk or CD-ROM, mark the outside of the disk or CD-ROM as CBI and identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to the complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

3. *Electronic access to the draft Strategy document.* You may access the draft Strategy in regulations.gov at <http://www.regulations.gov>, under docket ID number: EPA-HQ-OPPT-2018-0265.

## **II. Background**

### *A. The OIG Report: EPA Needs a Risk-Based Strategy to Assured Continued Effectiveness of Hospital-Level Disinfectants*

On September 19, 2016, the EPA Office of Inspector General (OIG) issued a report (No. 16-P-0316) titled “EPA Needs a Risk-Based Strategy to Assured Continued Effectiveness of Hospital-Level Disinfectants.” In this report, the OIG provided two recommendations: (1) suspension of the Agency’s Antimicrobial Testing Program (ATP) until EPA completes the reregistration process for antimicrobial pesticides; and (2) the development of a risk-based strategy to ensure the effectiveness of hospital-level disinfectants once products are in the marketplace.

The OIG recommended that the strategy, at a minimum, include: (1) a framework for periodic testing after product registration; (2) a program scope that is flexible and responsive to current public health risks; (3) risk factors for selecting products to be tested; (4) a method/process for collecting samples for testing; and (5) a date to begin the risk-based post-registration testing. In response to the first recommendation, EPA suspended the ATP in November 2017.

### *B. How Was this Draft Strategy Developed?*

EPA developed the draft Strategy based on the general recommendations provided by the

OIG. The Agency held a public listening session on June 21, 2018 to seek preliminary input from stakeholders on their early thoughts for the development of the draft Strategy. The materials presented during the listening session were published and made available for public comment. The materials presented during the listening session as well as all submitted public comments are available at <http://www.regulations.gov>, under docket ID number: EPA-HQ-OPPT-2018-0265.

### **III. Overview**

#### *A. What is the Antimicrobial Performance Evaluation Program Draft Strategy?*

This draft Strategy employs a risk-based approach to inform the Agency on the prioritization and selection of hospital-level disinfectants and associated label claims for testing. The proposed risk-based criteria consist of the following in order of priority: (1) product label claims for specific microbes and disease prevalence data; (2) evaluation of uncommon label claims and unique product application processes; and (3) evaluation of products tested using new and/or recently revised methods. The following additional refinement factors may also be considered to further prioritize product selection and testing: (a) issues identified during post-registration, product reregistration, and registration review; (b) trends observed under the previous testing program (ATP); and (c) products with high production volumes. Improving the product selection process and evaluating specific label claims of critical importance to public health are key features of the proposed testing program.

The Agency is considering the following two options individually or in combination for obtaining samples for testing: (1) EPA purchase of products in the marketplace, and (2) product samples provided by the registrant. Several options for allocating efficacy and chemistry testing resources may be utilized individually or in combination; these options include: (1) Office of Pesticide Programs Microbiology Laboratory and the Analytical Chemistry Laboratory, (2)

interagency agreements and contracts; (3) third party verification testing; and (4) registrant testing; and/or Data Call-Ins. EPA proposes to issue multi-year workplans two years prior to implementation to allow for public review and comment. At the end of testing, the Agency will provide the registrant with a memo summarizing the results and next steps attached to the Biological Report of Analysis detailing product specific results. A summary table will be published on the APEP website to communicate the testing results to the public. The Agency plans to begin implementation of the new risk-based testing program by 2022 when the initial round of registration review is completed.

The Agency will maintain flexibility responding to evolving healthcare issues that may require the risk factors to be updated periodically as new, relevant information becomes available. The Agency is soliciting feedback on the proposed draft Strategy to include specific questions (Unit III.B). As necessary, respondents may propose alternatives to the recommendations described in the draft Strategy, and the Agency will consider them for inclusion appropriateness on a case-by-case basis.

At places in these guidance documents, the Agency uses the word “should.” In this document, use of “should” with regard to an action means that the action is recommended rather than required.

#### *B. What Topics is the Agency Seeking Public Input On?*

The Agency is particularly interested in input from all interested stakeholders related to the following questions:

##### Focus Questions

1. Please comment on the proposed risk factors and refinements, their proposed prioritization, their strengths and limitations, and recommendations for other risk factors not

considered.

2. Are the options provided for sample collection suitable for the purpose of the testing program, and if not, what approaches would you suggest to optimize sample collection. Please provide advantages and disadvantages to your recommendations as appropriate.

3. Should the Agency and/or stakeholders conduct the laboratory evaluation (formulation chemistry and product efficacy) of disinfectant products? Provide examples to support your opinions and itemize situations where one approach would be more favorable versus the other.

4. Please comment on the flexibility and feasibility of the example workplan approach (See Appendix A, draft Strategy).

5. Please comment on the proposed communication strategy to convey test results to registrants and the general public including the preferred frequency of updates.

6. Please provide suggested routes for resolution of efficacy failures. Previously, these were addressed by “regulatory fixes” to include retesting, label amendments, etc.

#### **IV. References**

Documents that are referenced in the draft Strategy document can be found at <http://www.regulations.gov>, under docket ID number: EPA-HQ-OPPT-2018-0265. The docket includes these documents and other information considered by EPA. For assistance in locating any of these documents, please consult the persons listed under **FOR FURTHER INFORMATION CONTACT**.

**List of Subjects:** Environmental protection, Administrative practice and procedure, Pesticides.

**Dated:** September 26, 2019.

**Alexandra Dapolito Dunn,**

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